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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,032	11/24/2003	James A. Goldstein	60018300-0010	4750

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EXAMINER
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JOHNSTON, PHILLIP A

ART UNIT	PAPER NUMBER
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2881

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/721,032	<b>Applicant(s)</b> GOLDSTEIN, JAMES A. 	
	<b>Examiner</b> Phillip A Johnston	<b>Art Unit</b> 2881	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 21-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8-10-2004</u> . | 6) <input type="checkbox"/> Other: _____  |

***Detailed Action***

***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 21-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U. S. Patent No. 6,653,648, and claims 1-19 of U.S. Patent No. 6,448,571. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is obvious to one of ordinary skill in the art that all the limitations in Claims 21-46 of Application No. 10721032 are contained in Claims 1-20 of U. S. Patent No. 6,653,648, and claims 1-19 of U.S. Patent No. 6,448,571.

By way of example, a comparison of Claims 21-24 of Application No. 10721032, with Claim 1 of U. S. Patent No. 6,653,648, and claims 1 and 8 of U.S. Patent No. 6,448,571 is included below.

Claims 21-25 of Application No. 10721032, read as follows:

21. (Previously Presented) A method of performing a medical procedure, said method comprising: providing a radiation-shielding cubicle having an interior defining a medical personnel region and including a first wall having an opening therein; locating the cubicle with respect to an x-ray table so a portion of the x-ray table extends through the opening into the interior of the cubicle; and separating medical personnel from an x-ray emitter disposed outside of the cubicle using the first wall to shield the medical personnel from radiation emitted by the x-ray emitter.

22. (Previously Presented) A method in accordance with claim 21 further comprising joining the x-ray table to the cubicle using a radiation-shielding flexible interface.

23. (Previously Presented) A method in accordance with claim 22 wherein said joining the x-ray table to the cubicle using a radiation-shielding flexible interface comprises joining the x-ray table to the first wall using the radiation shielding flexible interface.

24. (Previously Presented) A method in accordance with claim 21 further comprising sealing the opening in the first wall using a flexible radiation-resistant skirt.

Claim 1 of U. S. Patent No. 6,653,648, read as follows;

Claim 1. A radiation protection system for shielding medical personnel from x-rays from an x-ray emitter while working on a patient, comprising:

an x-ray table having a first side, a second side and a top surface, the top surface for supporting a patient;

a radiation-shielding cubicle having an interior defining a medical personnel region, the cubicle having a ceiling, floor, a first wall for separating the medical personnel from an x-ray emitter disposed outside of the cubicle, a second wall extending from one end of said first wall adjacent to a first side of the x-ray table and a third wall extending from the first wall adjacent to a second side of the x-ray table, the first wall having an opening for locating a portion of the x-ray table into the interior of the cubicle;

a radiation-shielding screen attached to the x-ray table for covering the portions of the patient and the top surface of the x-ray table located in the interior of the cubicle;

a radiation-shielding flexible interface for joining the x-ray table to the cubicle, the flexible interface having a flexible radiation-resistant skirt sealing the opening; and an integrated procedural environment.

Claims 1 and 8 of U.S. Patent No. 6,448,571

Claim 1. A radiation protection system for shielding medical personnel from most radiation from an x-ray emitter and from x-ray scattering during radiologic procedures in which the medical personnel operate in close proximity to patient on an x-ray table, comprising:

a radiation-shielding wall separating the medical personnel from the x-ray emitter and having an opening around the x-ray table;

a radiation-shielding screen attached to the x-ray table and interposed between the patient and the medical personnel; and

a radiation-shielding flexible interface joining said wall with the x-ray table and said screen, said flexible interface having a flexible radiation-resistant skirt covering said opening in said wall.

Claim 8. A radiation protection system for shielding medical personnel from most radiation from an x-ray emitter and from x-ray scattering during radiologic procedures in which the medical personnel operate with surgical equipment in an operating region adjacent to a patient on an x-ray table, comprising:

a radiation-shielding cubicle surrounding the medical personnel in the operating region and extending over the x-ray table adjacent to the operating region, said cubicle having a wall with an opening around the x-ray table;

a radiation-shielding screen attached to the x-ray table and interposed between the x-ray table and the medical personnel; and

a radiation-shielding flexible interface circumferentially joining said cubicle with the x-ray table and said screen, said flexible interface having a flexible radiation-resistant skirt covering said opening in said wall.

It is obvious to one of ordinary skill in the art that all the limitations in claims 21-24 of Application No. 10721032 are for the most part, contained in claim 1 of U.S.

Patent No. 6,653,648, and Claims 1 and 8 of U. S. Patent No. 6,448,571.

***Claims Rejection – 35 U.S.C. 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

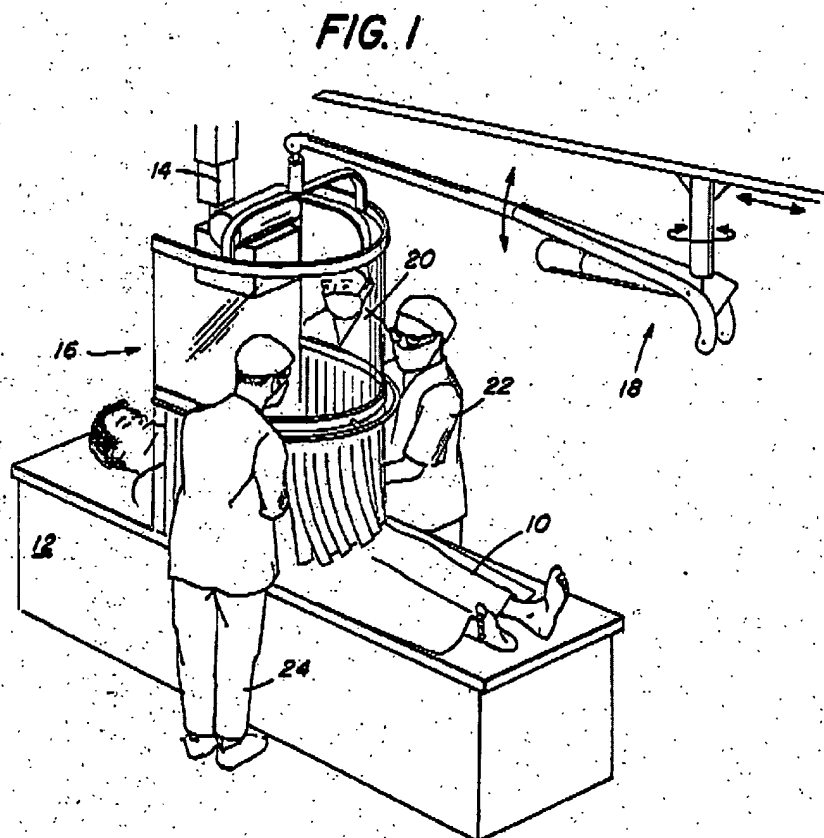
4. Claims 21-30,32,34,37-42,and 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,581,538, to Lenhart.

Lenhart (538) clearly discloses in FIG. 1, a special procedure room (the cubicle of claim 1 and 44) for angiographic examinations (the catheterization of claim 30), where patient 10 lying on table 12 is positioned with his torso in the line of X-rays delivered from conventional source 14. Shield 16, suspended from suspension system 18 is positioned to shield medical personnel 20, 22, 24 from X-rays traveling directly from source 14 or scattered from the air, from the patient, or from reflective surfaces in the vicinity of the work area. See Column 2, line 24-33; and Figure 1, below.

Lenhart (538) also discloses that, the flexibility of flaps 48 and 52 permits them to be draped (the flexible skirt of claims 22-27) over patient 10 and table 12 to form a continuous barrier ( the wall and barrier of claims 21,39,41, and 42) to the penetration of X-rays beyond the work area thus shielding medical personnel 20, 22, 24. Several medical personnel at one time, can observe the patient, participate in a procedure, and move freely about the patient, with their entire bodies, including eyes, head and torso

shielded from the X-rays. If it becomes necessary to touch the patient, a hand can easily be reached in between flaps 48, 52 (the ports of claims 28-30) without moving shield 16, and with minimum exposure to radiation. See Column 3, line 12-33.

Lenhart (538) further discloses the use of a video camera 68, as recited in claim 32. See Column 3, line 35-47.



**Claims Rejection – 35 U.S.C. 103**



5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 31,35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,581,538, to Lenhart, in view of Heesch, U.S. Patent No. 6,325,538.

Regarding claim 31, Lenhart (538) as applied above fails to teach the use of radiation level detection within the procedure room (cubicle). However, Heesch (538) discloses that sensitive radiation detection devices have to be installed outside the confinements of the radiation field isolator, in order to prevent accidental exposure of the operators to scatter radiation leaks. See Column 11, line 50-54.

Therefore it would have been obvious to one of ordinary skill in the art that the radiation shield of Lenhart (538) can be modified to use radiation detectors in accordance with Heesch (538), to prevent accidental exposure of the operators.

Regarding claims 35 and 36, Lenhart (538) as applied above fails to teach the use of a vascular access drape. However, Heesch (538) discloses that the waist collar 96 has to be quite flexible, and the entire lower portion of this part has to be covered in sterile sheets, in order to allow the operator to move the region of vascular access into

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the radiation field for x-ray guidance, should this become necessary due to access problems. See Column 11, line 19-54.

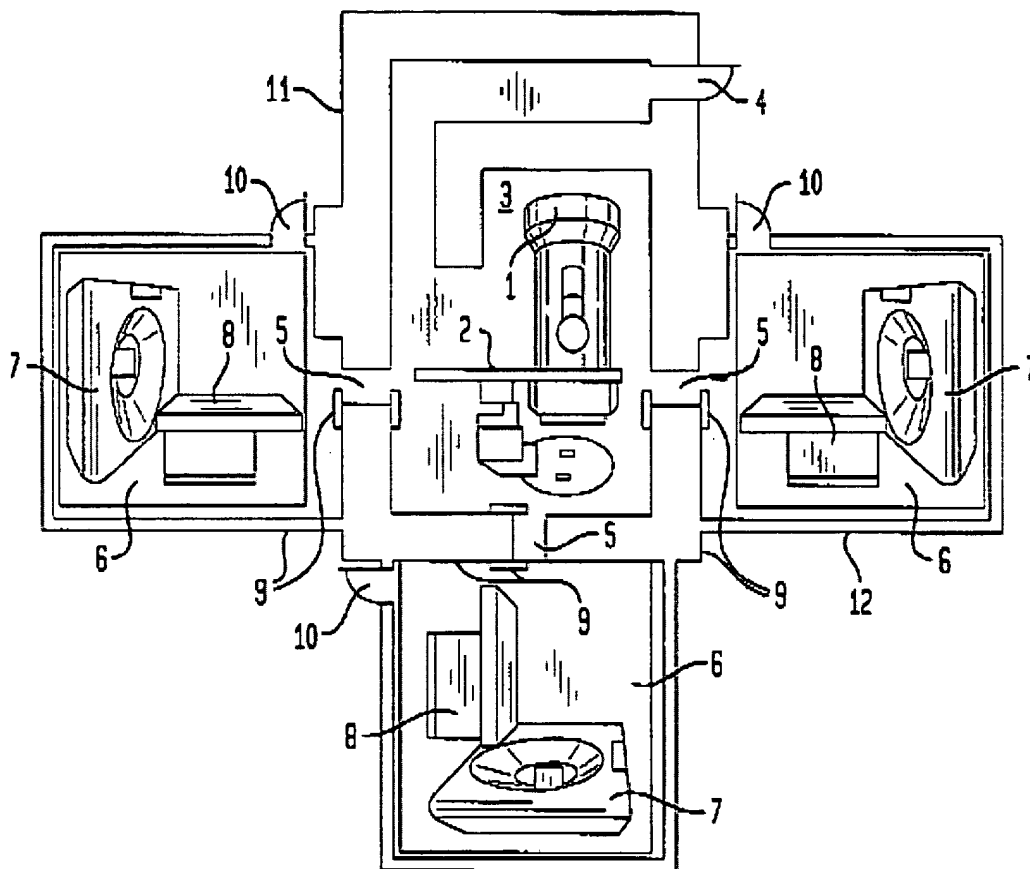
Therefore it would have been obvious to one of ordinary skill in the art that the radiation shield of Lenhart (538) can be modified to use the vascular access shield in accordance with Heesch (538), to move the region of vascular access into the radiation field for x-ray guidance.

7. Claims 33 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,581,538, to Lenhart in view of Sahadevan, U.S. Patent No. 5,851,182.

Lenhart (538) fails to teach the use of a planar wall as a shield. However, Sahadevan (182) discloses the use of planar shielding walls 11 and 12 to separate a radiation therapy accelerator room from surrounding CT scan rooms, and openings 5 for the treatment table 2 to pass through. See Column 10, line 1-19; and Figure 1 below.

Therefore it would have been obvious to one of ordinary skill in the art that the radiation shield of Lenhart (538), can be modified to use the barrier wall of Sahadevan (182) to provide a dividing wall with an opening to allow communication between two treatment rooms.

**FIG. 1**



Regarding claim 43, Lenhart (538) fails to teach the use of a two way microphone to communicate with the patient inside the shield. However, Sahadevan (182) discloses that a microphone and speakers at the control console maintain communication with the patient when the doors are closed. See Column 25, line 21-34.

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Therefore it would have been obvious to one of ordinary skill in the art that the radiation shield of Lenhart (538), can be modified to use the microphone system of Sahadevan (182) to maintain communication with the patient when the doors are closed.


### ***Conclusion***

8. Any inquiry concerning this communication or earlier communications should be directed to Phillip Johnston whose telephone number is (571) 272-2475. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiners supervisor John Lee can be reached at (571) 272-2477. The fax phone number for the organization where the application or proceeding is assigned is 703 872 9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PJ

August 10, 2004

  
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